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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/767,296

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50623.360

5005

7590 06/05/2008  
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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

06/05/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/767,296 | <b>Applicant(s)</b><br>YAN, JOHN Y. |  |
|                              | <b>Examiner</b><br>Julian W. Woo     | <b>Art Unit</b><br>3773             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 31-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 and 33-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28, 29, 31, 32 and 41-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 19, 2008 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 31, 32, 43, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Cosentino (4,405,319). Cosentino discloses, at least in figures 2 and 3 and in col. 1, lines 43-55 and col. 2, line 37 to col. 3, line 14; a stent (10) comprising a solid metallic region or solid core (11 and 12 combined), a porous metallic region or porous layer (30), and opposing or opposed first and second ends (on ends of cylinder 12) disposed along (i.e., adjacent to or alongside) or connected via a longitudinal seam (between 11 and 12) of the stent, where the porous metallic region is made from sintered particles (titanium powder according to col. 2, lines 44-46), and where the metallic porous region is an outermost layer. Note: Base claims 31 and 44 are

product-by-process claims (i.e., the stent is formed of a sheet), and the product (the stent) does not depend upon the process of making it.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 28, 29, 41 and 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosentino (4,405,319) in view of MacGregor (4,458,366). Cosentino discloses the invention substantially as claimed. Cosentino discloses a stent (10) comprising a strut element or cylinder (e.g., 12) including a solid metallic inner core (11 and 12 combined) having opposed inner and outer sides and an outer or outermost layer (30) disposed on the outer side, where the outer layer is made from a first porous metallic material (titanium), where the first porous metallic material is made from sintered particles (titanium powder), where the first porous layer faces radially outward and is configured such that a first agent contained in the first layer only permeates

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radially outward, and where the porous layer is adapted for being loaded with a therapeutic agent. However, Cosentino does not disclose that the strut or cylinder includes an inner layer made from a second porous, sintered metallic material or a second porous layer facing radially inward, where the second porous layer is configured such that a second agent contained in the second layer permeates radially inward. MacGregor teaches, at least in figures 1 and 2 and in col. 2, line 57 to col. 4, line 68 and col. 5, line 28 to col. 6, line 2, a blood access device with an inner layer (34) or a porous layer facing radially inward that is disposed on a solid metallic core (36) and comprises a second, sintered metallic material (e.g., a metal hydride according to col. 5, lines 49-53). MacGregor also teaches a porous outer layer according to col. 5, lines 57-65. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of MacGregor, to include an inner layer or a second porous layer on the strut or cylinder of Cosentino. Such a layer would reduce the risk of thromboembolism from blood contacting the inner surfaces of the strut or cylinder, and it would allow the permeation of a second agent radially inward and into the blood.

Note: Claims 28 and 48 are product-by-process claims (i.e., the strut is formed from a sheet and the seam is a weld), and the product (the strut or cylinder) does not depend upon the process of making it. Also, the recitation that an element is “configured” or “adapted” to perform a function is not a positive limitation, but only requires the ability to so perform.

6. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cosentino (4,405,319). Cosentino discloses the invention substantially as claimed, but

does not disclose that the pore size of the porous metallic region is 2 to 4 microns. Nevertheless, Cosentino discloses, in col 2, lines 46-48; that "[p]ore size should be sufficient to permit tissue ingrowth but not so large that adhesion is lost." Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to size the pores as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

### ***Response to Amendment***

7. Applicant's arguments with respect to claims 28, 29, 31, 32, and 41-49 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773

June 4, 2008